

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

SAN FRANCISCO HEALTH PLAN,	:	
	:	Case No.:
Plaintiff,	:	
vs.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.;	:	
CEPHALON, INC.; JOHNSON & JOHNSON;	:	
JANSSEN PHARMACEUTICALS,	:	
INC.; ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC n/k/a JANSSEN	:	
PHARMACEUTICALS, INC.; JANSSEN	:	
PHARMACEUTICA, INC. n/k/a JANSSEN	:	
PHARMACEUTICALS, INC.; ENDO	:	
HEALTH SOLUTIONS, INC.; ENDO	:	
PHARMACEUTICALS, INC.; PAR	:	
PHARMACEUTICAL, INC.; PAR	:	
PHARMACEUTICAL COMPANIES, INC.	:	
QUALITEST PHARMACEUTICALS, INC.;	:	
ALLERGAN PLC f/k/a ACTAVIS PLC;	:	
ACTAVIS, INC. f/k/a WATSON	:	
PHARMACEUTICALS, INC.; WATSON	:	
LABORATORIES, INC.; ACTAVIS LLC;	:	
ACTAVIS PHARMA, INC. f/k/a WATSON	:	
PHARMA, INC.; MALLINCKRODT, PLC;	:	
MALLINCKRODT, LLC; SPECGX LLC;	:	
MCKESSON CORPORATION; CARDINAL	:	
HEALTH, INC.; AMERISOURCEBERGEN	:	
CORPORATION; and WALGREENS BOOTS	:	
ALLIANCE, INC. A/K/A WALGREEN CO.	:	
	:	
Defendants.	:	

COMPLAINT

Plaintiff, San Francisco Health Plan (“Plaintiff”), by and through undersigned counsel, hereby sues defendants Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc.; Janssen Pharmaceutica, Inc. n/k/a/ Janssen Pharmaceuticals; Endo Health

Solutions, Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Qualitest Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt, PLC; Mallinckrodt, LLC; SpecGx LLC (collectively, the “Manufacturer Defendants”); McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Corporation; and Walgreens Boots Alliance, Inc. a/k/a Walgreen Co. (collectively, the “Distributor Defendants”) and alleges as follows:

INTRODUCTION

1. Plaintiff spends hundreds of millions of dollars each year on the health care, pharmaceutical care, and other necessary services and programs on behalf of its members, including payments for prescription opium-like painkillers (“opioids” or “Opioid drugs”), which are manufactured, marketed, promoted, sold, and/or distributed by the Manufacturer Defendants and Distributor Defendants (collectively, the “Defendants”).

2. Plaintiff provides health insurance coverage for more than 145,000 members in San Francisco County, California. Plaintiff pays to cover the welfare of its members through which it pays part or all of its members’ health care costs, including a substantial amount of opioid-related health care costs. These opioid-related health care costs include prescription drugs like opioids; substance abuse treatment, such as addiction and rehabilitation, overdose and alternative drug treatments; and emergency care.

3. Opioids include brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin. As such, they are highly addictive and dangerous and therefore are regulated as controlled substances by the United States Food and Drug Administration (“FDA”).

4. Opioids are believed to provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Opioids are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.

5. Defendants have manufactured, promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

6. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.¹ Throughout this Complaint, “addiction” refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

7. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer (“chronic pain”).

8. Defendants knew that, with prolonged use, the effectiveness of opioids wane over time, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.²

9. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized.

10. Upon information and belief, to date, there have been no long-term studies

¹ Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) (“DSM-V”).

² See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

demonstrating the safety and efficacy of opioids for long-term use.

11. Despite Defendants' foregoing knowledge, to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including common aches and pains such as lower back pain, arthritis, and headaches.

12. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive over recent years.

13. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that most patients could safely use opioids for chronic pain.

14. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

15. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.³ In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).⁴ While Americans represent only

³ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: <http://www.cdc.gov/drugoverdose/epidemic/index.html> (accessed September 19, 2017) (internal footnotes omitted).

⁴ M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.⁵ By 2014, nearly two million Americans either abused or were dependent on opioids.⁶

16. Defendants' campaign has been extremely profitable for them. In 2012 alone, opioids generated \$8 billion in revenue for drug companies.⁷

17. On the other hand, Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses in the United States.

18. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.⁸ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.⁹

19. Opioid addiction and overdoses have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."¹⁰

⁵ L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).

⁶ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: <http://www.cdc.gov/drugoverdose/opioids/prescribed.html> (accessed September 19, 2017).

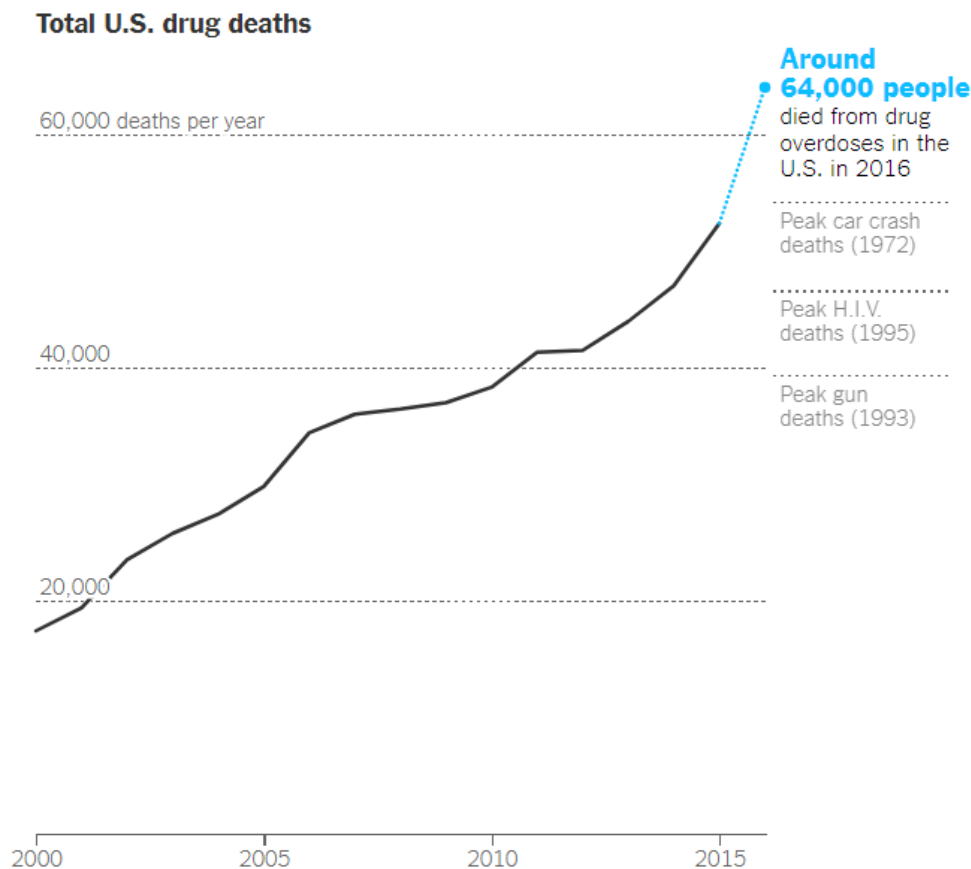
⁷ B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

⁸ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁹ J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) *Addiction* 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) *Journal of Addictive Diseases* 185 (2011).

¹⁰ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed September 19, 2017).

20. In 2016, approximately 64,000 people died from drug overdoses in the United States, more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths.¹¹ 66% of the drug overdose deaths in 2016 involved opioids, with the total deaths involving opioids taking more lives than breast cancer.¹² The total overdose deaths in 2016 were 10,000 more than in 2015. The graph below shows the trend relating to overdose deaths since 2000:¹³



21. Despite the record profits generated from their efforts, Defendants' marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no

¹¹ Katz, Josh, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html> (published September 2, 2017, accessed October 27, 2017).

¹² Kounang, Nadia, *Opioids now kill more people than breast cancer*, <http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html> (accessed December 29, 2017).

¹³ Katz, Josh, *The First County of Fentanyl Deaths in 2016: Up 540% in Three Years*, *Supra*.

overall change in the amount of pain that Americans report.¹⁴

22. The National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*.”¹⁵ As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes “ are not really independent causative factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

23. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion,¹⁶ and the commission of crime to obtain opioids throughout the United States. Consequently, public health and safety throughout the United States, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug. Plaintiff has been severely injured by these effects.

24. Plaintiff has not been an exception to the suffering caused by the opioid epidemic. The economic impact of over-prescribing opioids and opioid overdoses on Plaintiff reflects national and statewide trends. An excessive amount of Plaintiff’s funds have been used to treat

¹⁴ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

¹⁵ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> (accessed September 19, 2017) (emphasis added).

¹⁶ According to the CDC, when prescription medicines are obtained or used illegally, it is called “drug diversion.”

members affected by the abuse of opioids. As a direct and foreseeable consequence of Defendants' egregious conduct, Plaintiff paid and continues to pay, millions of dollars annually for health care costs resulting from over-prescribing opioids and prescription opioid dependency created by Defendants' deceptive marketing campaign and sales activities. These costs include, but are not limited to, unnecessary and excessive opioid prescriptions, substance abuse treatment services and inpatient hospital services. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

25. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; and (4) and costs associated with providing care for children born to opioid addicted mothers or raised by parents suffering from opioid-related disability or incapacitation.

26. These damages have been suffered, and continue to be suffered directly, by the Plaintiff. In sum, Plaintiff seeks restitution; damages; civil penalties; attorneys' fees; costs; and expenses.

27. Plaintiff also seeks any other relief to which it is entitled.

JURISDICTION AND VENUE

28. This Complaint was filed as an original action in this District.

29. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the

federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

30. This Court has personal jurisdiction over Defendants because they conduct business in the State of Ohio, purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

31. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (N.D. Ohio 1998); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

32. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965, because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

THE PARTIES

PLAINTIFF:

33. San Francisco Health Plan is a public, not-for-profit Medicaid HMO health plan that provides health care services to low-income San Francisco County residents.

34. Plaintiff has its principal office and regular place of business located at 50 Beale Street, 12th Floor, in San Francisco California, 94119.

35. Plaintiff provides health insurance coverage for more than 145,000 members. Plaintiff pays part or all of its members' health care costs, including a substantial amount of opioid-related health care costs including prescription drugs such as opioids, substance abuse treatment, such as addiction and rehabilitation, overdose and alternative drug treatments, and emergency care.

36. Plaintiff brings this action on its own behalf and also as subrogee of its members and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of its subrogors. In making the payments it has made on behalf of its members, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of their interests.

DEFENDANTS:

A. MANUFACTURER DEFENDANTS

37. The Manufacturer Defendants are defined above in the first paragraph of this Complaint. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

38. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a

wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”), an Israeli corporation.

39. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

40. Teva USA and Cephalon, Inc. (collectively, “Cephalon”) work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in this District, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), both Schedule II drugs.

41. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in this District.

42. Defendant Johnson & Johnson (“J&J”) is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

43. Defendant Janssen Pharmaceuticals, Inc. (“Janssen Pharmaceuticals”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

44. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil- Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

45. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

46. Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

47. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

48. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in this District, including Duragesic (Fentanyl), Nucynta (Tapentadol), and Nucynta ER (Tapentadol extended release), all of which are Schedule 2 drugs.¹⁷

49. Upon information and belief, together, Nucynta and Nucynta ER have had annual sales exceeding \$100 million. Upon information and belief, during material years, Duragesic accounted for at least \$1 billion in annual sales.

50. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

51. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

52. Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

53. Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International PLC. in September 2015 and is an operating company of Endo International PLC.

¹⁷ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

54. Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., and Par Pharmaceutical and their DEA registrant subsidiaries and affiliates (collectively, “Endo”) manufacture opioids, including Opana ER (Oxymorphone hydrochloride extended release), Opana (Oxymorphone hydrochloride), Percodan (Oxymorphone hydrochloride and aspirin), and Percocet (Oxymorphone hydrochloride and acetaminophen), which are sold nationally, and in San Francisco County.

55. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

56. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012, accounting for over 10% of Endo’s total revenue; Opana ER (one of Endo’s opioids) yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

57. Qualitest Pharmaceuticals, Inc. (“Qualitest”) is a wholly owned subsidiary of Endo. Qualitest is an Alabama corporation with its principal place of business in Huntsville, Alabama.

58. Allergan PLC is a public limited liability company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013 and then to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its

principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts; profits from the sale of Allergan/Actavis products; and ultimately benefits from them (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are collectively referred to as “Actavis.”).

59. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) and Norco nationally and in this District. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

60. Mallinckrodt, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

61. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the New York Secretary of State to do business in New York. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, PLC. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare).

62. SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt PLC. Mallinckrodt PLC, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together

“Mallinckrodt”) manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States, and in San Francisco County. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

63. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names “M,” “roxies/roxys” or “blues”). In July 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

B. DISTRIBUTOR DEFENDANTS

64. The Distributor Defendants are defined above in the first paragraph of this Complaint. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges that the unlawful conduct by the Distributor Distributors is responsible for the volume of prescription opioids plaguing the United States and its territories.

65. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California.

66. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers

across the country and, upon information and belief, within this District to pharmacies and institutional providers. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion. McKesson does substantial pharmaceutical business in Ohio and has more than 40,000 customers nationally.

67. Defendant Cardinal Health Inc. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio.

68. Cardinal does substantial pharmaceutical business in Ohio.

69. Defendant AmerisourceBergen Drug Corporation (“Amerisource”) is a Delaware Corporation with its corporate headquarters in Chesterbrook, Pennsylvania.

70. Amerisource does substantial pharmaceutical business in Ohio.

71. Defendant Walgreens Boots Alliance, Inc., also known as Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in San Francisco County specifically.

72. Walgreens is the second-largest pharmacy store chain in the United States, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

73. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other

prescription opioids to be diverted for abuse and illegal black-market sales.¹⁸

74. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

75. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.¹⁹

76. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.²⁰

77. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant

¹⁸ Press Release, U.S. Dep't of Just., U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act, (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-payrecord-settlement-80-million-civil-penalties-under-controlled>.

¹⁹ Appendix B of Order to Show Cause and Immediate Suspension of Registration, In the Matter of Walgreens Co. (Drug Enf't Admin. Sept. 13, 2012), https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf.

²⁰ *Id.*

Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.²¹

78. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).²²

79. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

80. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.²³

81. Defendants McKesson, Cardinal, and Amerisource are some of the largest opioid distributors in the United States and its territories.

82. The Distributor Defendants purchased opioids from manufacturers and sold them

²¹ *Id.*

²² Felice J. Freyer, Walgreens to Pay \$200,000 Settlement for Lapses with Opioids, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

²³ *Id.*

to pharmacies, which in turn sold them and were paid by Plaintiff.

83. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 C.F.R. § 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids.

84. The Distributor Defendants were each on notice that the controlled substances they distributed were susceptible to abuse and overuse and were not effective for long-term use.

85. The Distributor Defendants were each on notice that there was an alarming and suspicious increase in opioid distribution to retailers throughout the United States and its territories.

86. As entities involved in the distribution of opioid medications, the Distributor Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under federal law.

87. The Distributor Defendants had a duty to monitor suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies, including the Drug Enforcement Agency (“DEA”).

88. The Distributor Defendants failed in their duty to take action to prevent or reduce the distribution of these drugs.

89. The Distributor Defendants were in a unique position and had a duty to monitor, report, or otherwise limit the flow of these drugs throughout the United States and its territories.

90. The Distributor Defendants were warned in 2006 and 2007 by the DEA about their responsibility to avoid filling suspicious orders.

91. The Distributor Defendants, in the interest of their own massive profits,

intentionally failed in this duty.

92. The Distributor Defendants are members of the Healthcare Distribution Management Association (“HDMA”). The HDMA created “Industry Compliance Guidelines”, which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

93. The extraordinary increase in the volume of opioid pain medications distributed to nationwide retailers should have put the Distributor Defendants on notice to investigate and report such orders.

94. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers throughout the United States and its territories, which was a proximate cause of Plaintiff paying for inappropriate opioid prescriptions.

95. The Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of users throughout the United States and its territories.

96. The Distributor Defendants made substantial profits from the opioids paid for by Plaintiff.

97. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of Plaintiff’s members and other users throughout the United States and its territories.

98. The Distributor Defendants have abandoned their duties imposed under the law;

taken advantage of a lack of DEA law enforcement; and abused the privilege of distributing controlled substances to members of Plaintiff or their pharmacies.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

99. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation world-wide. Opioids, similar to the illegal drugs opium and heroin, are substances that act on opioid receptors to produce morphine-like effects.

100. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,²⁴ and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

101. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the DEA since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

102. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids: scientists observed negative outcomes from long-term opioid therapy in pain management

²⁴ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed a tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

103. In 1986, Dr. Russel Portenoy, M.D., who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”²⁵

104. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*²⁶

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject

²⁵ R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

²⁶ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”²⁷

105. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.”²⁸

106. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

107. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are “frighteningly high.”²⁹ At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

²⁷ *Id.*

²⁸ J. Loeser, Five crises in pain management, *Pain Clinical Updates*, 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety? 6 *J. Pain Research* 513, 514 (2013)).

²⁹ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) *Archives of Internal Med.* 1422 (2010).

108. Opioids vary by duration. Long-acting opioids, such as Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

109. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

110. The highly addictive nature of opioids were well known to each of the Defendants for many years during their deceptive marketing campaign, yet Defendants concealed the addictive nature from Plaintiff and others while all along generating combined revenues of billions of dollars.

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS.

111. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have intentionally failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

112. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function on a long-term basis. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

113. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other, non-addicting, treatments.³⁰

114. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

115. Although opioids may work acceptably well during a limited, short period of time, long-term usage results in marked declines in patient's ability to function, their general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.³¹

116. The foregoing is true both generally and for specific pain-related conditions. Studies of the long-term use of opioids for chronic lower back pain have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not permit patients to return to work or physical activity. This failure is due in part to addiction and other side effects.

117. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment,

³⁰ A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

³¹ See A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other, non-opioid medications.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

118. Prior to the Defendants' marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term, temporary basis in order to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.

119. By its very nature, the market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell their opioid products for both short term pain relief and for the treatment of long-term, chronic pain, they could achieve blockbuster levels of sales while exponentially increasing their profits. Further, Defendants recognized that the elevated risk of addiction associated with the long-term use of their highly-addictive, opioid products virtually guarantee that their blockbuster profits would continue indefinitely.

120. Defendants knew that to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. In other words, Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

121. Defendants knew that their goal of increasing profits by promoting the prescription

of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors such as Plaintiff.

122. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort and pervert medical and public perception of existing scientific data.

123. Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses (“CMEs”), and other “educational” materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but patently false “consensus” supporting the long-term use of opioids.

D. DEFENDANTS USED “UNBRANDED” MARKETING TO EVADE REGULATIONS AND CONSUMER PROTECTION LAWS.

124. Pharmaceutical companies’ promotional activity can be branded or unbranded; unbranded marketing typically focuses on education regarding a particular disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in its communications, drug companies avoid the extensive regulatory framework governing branded communications.

125. A drug company’s branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug’s

benefits and risks.³² The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of prescribing those drugs to their patients.

126. Further, the Federal Food, Drug, and Cosmetic Act (“FDCA”) places additional restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are “misbranded.” A drug is “misbranded” if it lacks “adequate directions for use” or if the label is false or misleading “in any particular.”³³ “Labeling” includes more than the drug’s physical label; it also includes “all . . . other written, printed, or graphic matter . . . accompanying” the drug, including promotional material.³⁴ The term “accompanying” is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug.³⁵ Thus, Defendants’ promotional materials are part of their drugs’ labels and are required to be accurate, balanced, and not misleading.

127. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that a drug’s marketing materials are misleading, it can issue either an untitled letter or a warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

128. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants intentionally avoided branded

³² 21 U.S.C. 352(a); 21 C.F.R. § 202.1(e)(6); 21 C.F.R. § 202.1(e)(3); 21 C.F.R. § 1.21(a)

³³ 21 U.S.C. 352(f); 21 U.S.C. 352(q); *U.S. v. Sullivan*, 68 S.Ct. 331, 335 (1948)

³⁴ 21 U.S.C.A. § 321(m)

³⁵ *Kordel v. U.S.*, 69 S. Ct. 106, 110 (1948)

promotional materials for the express purpose of escaping regulatory review of their claims.

129. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

130. By acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, Defendants would cite to these sources as “independent” corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not “push back” at having materials, for example, from the non-profit American Pain Foundation (“APF”) on display in their offices, as they would with drug company pieces.

131. As part of their marketing scheme, Defendants spread and validated their deceptive messages through the following unbranded vehicles (“the Vehicles”): (i) so-called “key opinion leaders” (*i.e.*, physicians who influence their peers’ medical practice, including but not limited to prescribing behavior) (“KOLs”), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported scientific literature, ghostwritten by Manufacturer Defendants and published by KOLs ; (iii) treatment guidelines ghostwritten by Manufacturer Defendants and published as a direct result of KOLs reputation and involvement with the publishing organizations; (iv) CMEs by KOLs, attended by local physicians; and (v) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations (“Front Groups”), which were deliberately influenced by Defendant-

controlled KOLs exercising their influence both directly and indirectly because they served in leadership roles in these organizations.

132. Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

133. Even where such unbranded messages were disseminated through third-party Vehicles, including the KOLs, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials all Defendants knew were false, misleading, unsubstantiated, unbalanced, and incomplete from the very outset of the message's "creation" by the purportedly independent KOLs. As described herein, Defendants' sales representatives distributed third-party marketing material to Defendants' target audience that was deceptive.

134. Defendants took an active role in writing, guiding, reviewing, and approving many of the misleading statements issued by third parties, including the KOLs' statements, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain. The process described in this paragraph is commonly referred to as "Ghostwriting."

135. The unbranded marketing materials that Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks. All of these unbranded marketing materials were promoted by the KOLs falsely from the very outset as independent statements. The KOLs' false promotion of independence provided the unbranded marketing materials utilized by Manufacturer

Defendants the credibility required to fraudulently induce physicians to prescribe opioids for chronic pain.

a. *Manufacturer Defendants' Misuse of KOLs*

136. The Manufacturer Defendants cultivated a select circle of doctors who were chosen and sponsored by Manufacturer Defendants solely because they promoted the aggressive treatment of chronic pain with opioids in return for the payment of vast sums of money by the Manufacturer Defendants. As set forth herein, the pro-opioid, KOLs have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through the KOLs, each of whom accepted money to promote the false marketing claims of Defendants.

137. In return for their successful pro-opioid advocacy, KOLs received money, prestige, recognition, research funding, and avenues to publish. The more successful the KOLs' deceptive promotion of opioids for chronic pain, the more they were able to receive from the Manufacturer Defendants.

138. Defendants cited and promoted the KOLs and studies or articles by the KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of truly independent doctors critical of the use of chronic opioid therapy.

139. Defendants carefully vetted their KOLs to ensure that they would remain on-message and supportive of the agenda to falsely promote opioids as safe for the treatment of chronic pain. Defendants also kept close tabs on the content of the materials published by the KOLs, and often authored, edited, and/or revised them in their entirety prior to publication.

140. In their promotion of the use of opioids to treat chronic pain, the KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit the Defendants.

b. Defendants' Corruption of Scientific Literature through KOLs

141. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants, instrumentally relying on KOLs, misled physicians, patients, and health care payors into believing that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

142. To accomplish their goal, Defendants – sometimes through third-party consultants and/or Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) – commissioned, edited, and arranged for the placement of favorable articles in academic journals authored by KOLs.

143. Defendants' plans for these materials did not originate in the departments within their organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in

Defendants' marketing departments and with their marketing and public relations consultants, ultimately being published and promoted by KOLs.

144. In these materials, Defendants (and their KOL surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

145. Defendants also made sure that favorable articles published were disseminated and cited widely in the medical literature and by KOLs, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. For example, an item appeared in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"). Defendants, through the KOLs acting on their behalf, failed to reveal that the item was actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids:

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program

Waltham, MA 02154

Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

146. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain, making the data useless for any generalization regarding the safety or efficacy of Opioids for treating chronic pain. Even aside from chronic pain treatment, the letter notes that when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were followed, for how long. None of these serious limitations were disclosed when Defendants and the KOLs acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

147. Dr. Jick has complained that his letter has been distorted and misused – as indeed

it has been.

148. Defendants not only created and promoted favorable studies in the literature through the paid efforts of KOLs but, in order to discredit or suppress negative information, funded studies and articles that targeted articles contradicting Defendants' claims or raising concerns about chronic opioid therapy. In order to do so, Defendants – often with the help of KOLs – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

149. Defendants' strategy – to create, fund, plant, and promote supportive literature for citation as pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted their claims – was flatly inconsistent with their legal obligations. Defendants' strategy was intended to alter, and did alter, prescribing and consumer patterns, including those prescribers to members of Plaintiff by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

c. Defendants' Misuse of Treatment Guides

150. Treatment guidelines authored by KOLs under the direction and control of the Manufacturer Defendants have been particularly important in securing the medical community's acceptance of chronic opioid therapy. The guidelines are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not pharmaceutical experts and who generally have no special training in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors ("TPPs"), like Plaintiff, in determining whether they should pay for treatments for specific indications.

i. FSMB

151. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB also finances opioid- and pain-specific programs through grants from Defendants.

152. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 edition of the guidelines, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies” and taught that opioids were “essential” for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed.

153. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including those treating Plaintiff’s members.

154. The publication of *Responsible Opioid Prescribing* was backed largely by the Manufacturer Defendants. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the “leading continuing medical education (CME) activity for prescribers of opioid medications.”

155. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB’s *Responsible Opioid Prescribing*, which was drafted by a KOL named Dr. Scott Fishman, M.D. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates

LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and approved by drug company representatives, including the Manufacturer Defendants, and Dr. Fishman felt compelled to draft pieces which distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

156. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain – alone - would “reverse that effect and improve function.” However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

157. Defendants relied on 1998 Guidelines to convey the alarming message that “under-treatment of pain” could result in official discipline or criticism, but no discipline or criticism would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

ii. AAPM/APS GUIDELINES

158. American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which, upon information and belief, received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would

become addicted to opioids was low.³⁶ The Chair of the committee that issued the statement was Dr. J. David Haddox. The sole consultant to the committee was a KOL named Dr. Russel Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

159. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, M.D., received support from defendants Janssen, Cephalon, and Endo.

160. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated to those treating or prescribing to Plaintiff's members during the relevant time period.

161. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions or their roles in the development and implementation of the guidelines.

iii. GUIDELINES THAT DID NOT RECEIVE DEFENDANTS' SUPPORT

162. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding –

³⁶ Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77-79 (1997)

reached very different conclusions.

163. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians (“ASIPP”), warned that “[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”³⁷

164. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence.”³⁸

165. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”)

³⁷ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

³⁸ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids* (2011).

in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.³⁹

d. *Defendants' Misuse of CMEs*

166. CMEs are professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because KOLs typically teach CMEs, and with the support of Defendants become highly respected in their fields, the program is thought to reflect these physicians' medical expertise. As a result, CMEs can be especially influential with doctors. In fact, the KOLs used CMEs in California to influence the prescribing habits of doctors within California, including doctors who prescribed medications to Plaintiff's members.

167. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Through KOLs, Defendants particularly targeted general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

168. Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages

³⁹ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

169. The American Medical Association (“AMA”) has recognized that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urges that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”⁴⁰

170. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski, M.D., and Dr. Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.⁴¹ It instructed prescribers that “clinically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility,” and recommended dispensing “rapid onset opioids” for “episodes that occur spontaneously” or unpredictably, including “oral transmucosal fentanyl,” Actiq, and “fentanyl buccal table,” Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon’s speaker’s bureau.⁴² Dr. Fine also received funding from Cephalon for consulting services.

171. Physicians and affiliated healthcare providers treating Plaintiff’s members attended or reviewed Defendants’ sponsored CMEs during the relevant time period and were misled by

⁴⁰ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

⁴¹ Fine, Perry, et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News (2009), <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain> (accessed December 29, 2017).

⁴² 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from, *inter alia*, Janssen, Cephalon, and Endo.

them.

172. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Defendants could rely upon instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Defendants' Misuse of Patient Education Materials and Front Groups

173. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."⁴³ Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.⁴⁴ Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

174. Defendants entered into arrangements with numerous Front Groups to promote the prescription of opioids for the treatment of chronic pain. Each one of these Front Groups depends largely, if not exclusively, upon Defendants for significant funding and, in some cases, depend

⁴³ Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

⁴⁴ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

wholly upon Defendants' funding for their continued survival. In addition to generating Defendants' promotional materials and programs supporting chronic opioid therapy to be provided to doctors and patients, the Front Groups also assisted Defendants' marketing efforts by responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to treat chronic pain. Defendants created a symbiotic relationship with the Front Groups whereby Defendants funded them in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages. In turn, the supportive messages drove prescriptions and profits for Defendants and ensured continued funding of the Front Groups.

i. AMERICAN PAIN FOUNDATION

175. The most prominent and effective of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than \$10 million in funding from opioid manufacturers, including Defendant Manufacturers, from 2007 until it closed its doors in May 2012.

176. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain treatment and minimized their risks, specifically the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including Plaintiff's members.

177. By 2011, APF was dependent on incoming grants from defendants Cephalon,

Endo, and others to avoid using its line of credit. APF board member Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

178. While APF held itself out as an independent patient advocacy organization, it simultaneously engaged in grassroots lobbying against various legislative initiatives that would have regulated the prescription of opioids and protect patients from the risks associated with the unnecessary prescription of highly addictive and ineffective drugs. In stark contrast to its stated purpose, APF functioned principally as an advocate for the interests of Defendants, not patients.

179. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.

180. The intimate relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages strongly indicates that each Defendant that provided it with funding was able to exercise editorial control over its publications.

181. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links - financial and otherwise - between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately,"⁴⁵ proving the degree of its dependence upon Defendants' financing as well as their control over it.

⁴⁵ William Heisel, USC Annenberg Center for Health Journalism, Antidote: Investigating Untold Health Stories, *Journalists Bag a Big One: The American Pain Foundation*, <https://www.centerforhealthjournalism.org/blogs/2012/05/14/journalists-bag-big-one-american-pain-foundation> (accessed September 19, 2017).

ii. THE AMERICAN ACADEMY OF PAIN MEDICINE

182. The AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

183. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

184. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Fine, Dr. Portenoy, and Dr. Lynn Webster, M.D. Dr. Webster was elected president of AAPM while under a DEA investigation. Another past AAPM president, KOL Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are ... small and can be managed.”⁴⁶

185. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular

⁴⁶ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), <http://www.medscape.org/viewarticle/500829> (accessed September 19, 2017).

funding and the leadership of pro-opioid KOLs within the organization.

E. DEFENDANTS ACTED IN CONCERT WITH KOLs AND FRONT GROUPS TO CREATE, PROMOTE, AND CONTROL UNBRANDED MARKETING.

186. Like the tobacco companies that engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the industry-funded and directed Front Groups and KOLs to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superior efficacy of opioids to treat chronic pain.

187. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Despite knowing that this information was false and misleading, Defendants, Front Groups, and KOLs disseminated these misrepresentations nationwide, including to Plaintiff's prescribers and members.

188. One Vehicle for Defendants' marketing collaboration was the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

189. PCF is comprised of representatives from opioid manufacturers and distributors (including defendants Cephalon, Endo, and Janssen); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations — almost all of which received substantial funding from Defendants.

190. PCF, for example, developed and disseminated “consensus recommendations” for a Risk Evaluation and Mitigation Strategy (“REMS”) for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁴⁷ This was critical because a REMS that went too far in narrowing the uses or benefits or in highlighting the risks of chronic opioid therapy would undermine Defendants’ marketing efforts and adversely affect profits. The recommendations claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new barriers.” Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, rather than undermine, their deceptive marketing of opioids for chronic pain treatment.

F. DEFENDANTS’ MISREPRESENTATIONS

191. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, members of Plaintiff, and payors such as Plaintiff. These promotional messages were intended to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

192. Recognizing that doctors are the gatekeepers for controlling access to prescription drugs, not surprisingly, Defendants focused the bulk of their marketing efforts and multi-million-dollar budgets on the professional medical community. As a controlled substance with significant regulatory barriers limiting access, Defendants knew doctors would not prescribe opioids to

⁴⁷ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

patients with common chronic pain complaints unless doctors were convinced that opioids had real benefits and minimal risks. Accordingly, Defendants concealed from prescribers, patients, and the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Instead, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors prescribing to Plaintiff's members began prescribing opioids on a long-term basis to treat chronic pain – a treatment choice that most doctors and patients would not have considered prior to Defendants' campaign.

193. Drug company marketing materially impacts doctors' prescribing behavior.⁴⁸ Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs. As a result of Defendants' deceptive marketing, doctors who would not have otherwise prescribed opioids, ended up prescribing opioids for chronic pain.

194. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one survey published by the AMA, 88% of the practitioner respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities.⁴⁹ These results are the direct consequence of Defendants' fraudulent marketing

⁴⁸ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing how a positive impact on prescriptions was written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding that academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs).

⁴⁹ Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med.

campaign.

195. As described in detail below, Defendants:

- Misrepresented the truth about how opioids lead to addiction;
- Misrepresented that opioids improve function;
- Misrepresented that addiction risk of opioids can be managed;
- Misled doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- Falsely claimed that withdrawal is simply managed;
- Misrepresented that increased doses pose no significant additional risks to patients; and
- Falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

196. Defendants’ misrepresentations were aimed at doctors, patients, and payors.

197. Underlying each of Defendants’ misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants’ collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks existed.⁵⁰

a. *Defendants, Acting Individually and Collectively, Misrepresented the Truth About How Use of Opioids Leads to Addiction.*

198. Defendants’ fraudulent representation that opioids are rarely addictive is central to Defendants’ scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health

(Dec. 8, 2014), E1-E3.

⁵⁰ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

care payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for chronic pain. As both an intended and foreseeable result, doctors treating Plaintiff's members prescribed more opioids to more patients – thereby enriching Defendants.

199. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, despite the complete lack of supporting scientific evidence.

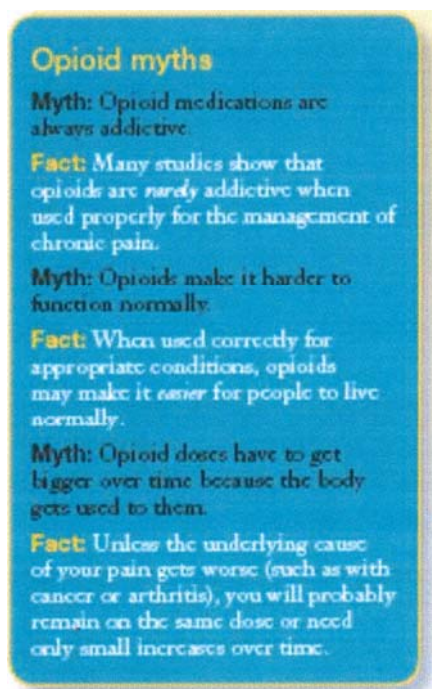
200. To wit, defendant Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which fraudulently claimed that addiction is rare and limited to extreme cases of unauthorized dose escalations, opioid prescription fraud, or theft.

201. Similarly, defendant Endo sponsored a website, www.painknowledge.com, through APF, which falsely claimed that: “[p]eople who take opioids as prescribed usually do not become addicted.” Although the term “usually” is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician.

202. Additionally, Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that “[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems.” This implies that patients prescribed opioids for *genuine* pain will not become addicted, a claim which is both unsupported and known to be false.

203. Likewise, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described the fact that opioids are addictive as a “myth” and falsely asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for

the management of chronic pain.”



Although the term “rarely” is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician, which is untrue. The guide states as a “fact” that “Many studies” show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

204. For another example, defendant Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications,” although the term “very unlikely” is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

205. Defendant Actavis’s strategy and pattern of deceptive marketing is similarly evident in its internal training materials. A sales education module titled “Kadian Learning

System” trained Actavis’s sales representatives on the marketing messages described above – including deceptive claims about improved function, the risk of addiction, the false scientific concept of “pseudoaddiction,” and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in California.

206. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that “most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy,” when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have necessitated increasing doses: “Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain].” Second, Actavis instructed its sales personnel that opioid “[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose.” Actavis failed to inform doctors, via its sales representatives, of the greater risks associated with opioids at high doses.

207. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers even before that date. A July 2010 “Dear Doctor” letter issued by the FDA indicated that “[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and

minimized serious risks associated with [Kadian].” Certain risks that the FDA noted were misrepresented include the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.” The FDA also took issue with an advertisement for misrepresenting Kadian’s ability to help patients “live with less pain and get adequate rest with less medication,” when the supporting study did not represent “substantial evidence or substantial clinical experience.”

208. Finally, the internal documents of another defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, and Actavis discussed the AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients, regardless of past abuse histories, amongst other deceptive statements as described above.

209. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients’ chronic pains with opioids were failing their patients and risking professional discipline, while doctors who prescribed long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that “exaggerated” concerns about the risk of addiction resulted in patients’ pain being under-treated while opioids were over-regulated and under-prescribed. The Treatment Options guide funded by Cephalon claims that “[d]espite the great benefits of opioids, they are often underused.”

210. *Let’s Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns, “strict

regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence.” The program goes on to say, “[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States.”

b. *Defendants, Acting Individually and Collectively, Misrepresented that Opioids Improve Function.*

211. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as- needed basis for breakthrough pain.

212. Although opioids may initially improve patients’ function by providing pain relief in the short term, no controlled studies of the use of opioids beyond 12 weeks has ever shown that opioids improve patients’ function in the long-term. On the contrary, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.⁵¹ Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients’ function and quality of life without disclosing the lack of evidence for this claim.

⁵¹ Jeffrey Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) *Spine* 2219-27 (Sept. 15, 2008).

213. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."⁵²

214. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies, including defendants Cephalon and Endo, deceptively taught that relief of pain in itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

215. Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (*e.g.*, Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently still available online.

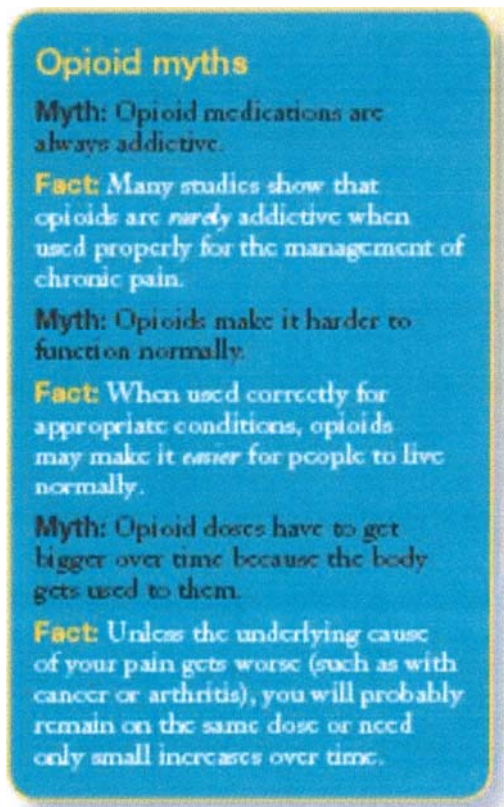
216. Through the APF, Endo sponsored a website, painknowledge.com, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

217. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and

⁵² Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA21-260 (March 24, 2008).

climbing stairs.

218. As set forth in the excerpt below, the guide states as a “fact” that “opioids may make it *easier* for people to live normally” (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.



219. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative despite the lack of statistical support.

220. Janssen provided grants to APP to distribute the publication *Exit Wounds* to veterans, which taught that opioid medications “increase your level of functioning” (emphasis in original).

c. *Defendants, Acting Individually and Collectively, Misrepresented that Addiction Risk can be Effectively Managed.*

221. Defendants each continue to maintain to this day that most patients can safely take opioids long-term for chronic pain relief without becoming addicted. Presumably to explain to doctors the high incidence of patient opioid addiction, Defendants have recently acknowledged that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they claim, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) and allow doctors to more closely monitor patients at greater risk of addiction.

222. There are three fundamental flaws in Defendants’ representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that the addiction risk screening tools currently available are reliable, effective, capable of being applied correctly and consistently, or invulnerable to patient manipulation. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through the screening tools can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients identified through such screening tools as “low risk” can take opioids long-term without significant danger of addiction.

223. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality (“AHRQ”), which “systematically review[ed] the current evidence on long-term opioid

therapy for chronic pain” identified “[n]o study” that had “evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse.”⁵³ Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening tests are not proven to work in the real world, even when the most well-intentioned doctors were misled to employ them.⁵⁴

224. Defendants’ misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively “GPs”), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011-2012 narcotic prescription data of the type regularly used by Defendants to market their drugs, that only 385 of the more than half million prescribers of opioids during that time period were identified as pain specialists.⁵⁵

225. In materials they produced, sponsored, or distributed, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more

⁵³ The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

⁵⁴ M. Von Korff, et al., *Long-term opioid therapy reconsidered*, 15595, *Annals Internal Med.* 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 *Pain Physician* S1 (2012).

⁵⁵ Express Scripts Lab, *A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain* (December 2014).

comfortable starting on opioid therapy for chronic pain. Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring – with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a "heads you lose; tails you lose" outcome for patients – all of whom are subjected to an unacceptable risk of addiction – and for payors, including Plaintiff.

226. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

227. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by KOL Dr. Webster and linked to Janssen or (b) the *Screening and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

d. *Defendants, Acting Individually and Collectively, Misled Physicians, Patients, and Payors Through the Use of the Term "Pseudoaddiction."*

228. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by KOL Dr. J. David Haddox and was popularized in opioid therapy for chronic pain by KOL Dr. Portenoy, who consulted for defendants Cephalon, Endo, and Janssen. Much of the same language appears in

other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

229. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

230. Cephalon sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

e. Defendants, Acting Individually and Collectively, Claimed Withdrawal is Simply Managed.

231. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – an adverse effect that also makes it less likely that patients will be able to stop using drugs.

232. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

233. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically

dependent would take longer than ten days – when and if it is successful at all.⁵⁶

f. Defendants, Acting Individually and Collectively, Misrepresented that Increased Doses Pose no Significant Additional Risks.

234. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were “frighteningly high,” suggesting that patients would eventually reach a stable, effective dose. Each of Defendants’ claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

235. In materials Defendants produced, sponsored or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors’ concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients’ treatment as doses escalated. These claims were not supported by scientific evidence.

236. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

237. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

⁵⁶ See Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

238. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."

g. Defendants, Acting Individually and Collectively, Deceptively Omitted or Minimized the Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

239. In materials they produced, sponsored or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers, patients, and payors would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims were supported by scientific evidence.

240. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,"⁵⁷ hormonal dysfunction;⁵⁸ decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;⁵⁹ neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic

⁵⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

⁵⁸ H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) *J. Pain* 377-84 (2001).

⁵⁹ Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, *Eur. J. Pub. H.* (July 31, 2014).

stress disorder and anxiety also often accompany chronic pain symptoms.⁶⁰

241. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure was closer to 3,200 at the time.⁶¹ *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

242. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

243. Janssen sponsored, and Endo provided grants, to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

244. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010

⁶⁰ Karen H. Seal, Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 940- 47 (2012).

⁶¹ Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.⁶²

245. The combined efforts of Defendants and KOLs to deceive the medical community resulted in Plaintiff also relying on the aforementioned false statements when it was induced to provide healthcare services for members that would treat chronic pain with opioid medications.

G. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE.

246. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which they called “detailers” to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and to prescribers for Plaintiff’s members. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

247. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors’ prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely

⁶² M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass’n Internal Med. 1573, 1573 (2013).

the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their pitches. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including to doctors prescribing to Plaintiff's members.

H. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFF AND ITS MEMBERS.

248. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

249. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

250. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover,

Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

I. DEFENDANTS FRAUDULENTLY CONCEALED THEIR MISREPRESENTATIONS.

251. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

252. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

253. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by Plaintiff.

254. Defendants also concealed their participation by extensively using the public

relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

255. Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

J. DEFENDANTS ENTERED INTO AND ENGAGED IN A CIVIL CONSPIRACY.

256. Defendants entered into an agreement to engage with a common purpose in the unlawful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

257. Defendants reached an agreement between themselves to act with a common purpose to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

258. This network is interconnected and interrelated, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

259. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids,

Defendants committed overt acts with a common purpose in furtherance of their conspiracy.

K. DISTRIBUTOR DEFENDANTS INTENTIONALLY FAILED TO TAKE ANY ACTION TO STOP THE MISUSE OF OPIOIDS, IN VIOLATION OF LAWS AND REGULATIONS.

260. The Distributor Defendants purchased opioids from manufacturers, such as the named Manufacturer Defendants herein, and sold them to pharmacies used by members of Plaintiff.

261. The Distributor Defendants played an integral role in the chain of opioids being distributed to members of Plaintiff.

262. 21 U.S.C. § 823 requires the Distributor Defendants to establish effective controls against orders, which the Distributor Defendants knew or should have known were likely to be diverted into the community Plaintiff serves.

263. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

264. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1).

265. Federal regulations impose a non-delegable duty upon wholesale drug distributors

to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

266. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

267. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

268. These prescription drugs are regulated for the purpose of providing a “closed” system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁶³

269. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.⁶⁴

270. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”⁶⁵

271. The Distributor Defendants have admitted that they are responsible for reporting

⁶³ See 1970 U.S.C.C.A.N. 4566, 4571-72.

⁶⁴ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited March 22, 2019). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited March 22, 2019).

⁶⁵ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

suspicious orders.⁶⁶

272. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”⁶⁷ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”⁶⁸ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”⁶⁹

273. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.⁷⁰ This letter reminds the Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”⁷¹ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

⁶⁶ See Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

⁶⁷ Rannazzisi Letter, *supra*, at 2.

⁶⁸ *Id.* at 1.

⁶⁹ *Id.* at 2.

⁷⁰ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

⁷¹ *Id.*

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.⁷²

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when

⁷² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), *Supra*.

determining whether an order is suspicious.”⁷³

274. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”⁷⁴

275. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.⁷⁵

276. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers that Plaintiff’s members use, and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to the community Plaintiff serves.

⁷³ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), *Supra*.

⁷⁴ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *2 [hereinafter Brief of HDMA].

⁷⁵ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

277. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.⁷⁶

278. The sheer volume of prescription opioids distributed to pharmacies in the community Plaintiff serves, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted the community Plaintiff serves, is excessive for the medical need of the community and facially suspicious, some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.⁷⁷

279. The Distributor Defendants failed to report “suspicious orders” originating from the community Plaintiff serves, or which the Distributor Defendants knew were likely to be diverted to the community Plaintiff serves, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

280. The Distributor Defendants unlawfully filled suspicious orders of unusual size that deviated substantially from a normal pattern and/or orders of unusual frequency in the community Plaintiff serves, and/or in areas from which the Distributor Defendants could foreseeably anticipate that opioids were likely to be diverted to the community Plaintiff serves.

281. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from the Plaintiff serves, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to

⁷⁶ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

⁷⁷ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

the community Plaintiff serves.

282. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

283. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities of suspicious orders when discovered, in violation of their duties under federal law.

284. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.⁷⁸

285. The laws at issue here are public safety laws.

286. The unlawful conduct by the Distributor Defendants is purposeful and intentional.

287. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

288. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

289. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under the law and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding the Distributor Defendants’ compliance with their

⁷⁸ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

legal duties.

290. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”⁷⁹
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”⁸⁰
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”⁸¹
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”⁸²
- e. The Associations alleged (inaccurately) that “DEA’s regulations [sensibly impose] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”⁸³
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors

⁷⁹ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.

⁸⁰ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983 at *8.

⁸¹ *Id.* at *14

⁸² *Id.* at *22

⁸³ *Id.* at *24-25

– which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”⁸⁴

291. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.⁸⁵

292. The Court of Appeals for the District of Columbia issued an opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218-219, 226. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

293. Wholesale Distributor McKesson was forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) entered into between McKesson and the DEA

⁸⁴ *Id.* at *26

⁸⁵ See Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”⁸⁶

294. Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”⁸⁷ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers” including the McKesson Distribution Centers located in 12 different locations, any of which could have foreseeably caused the diversion of opioids into California.⁸⁸ Due to these violations, McKesson agreed that its authority to distribute controlled substances from these 12 facilities would be partially suspended.⁸⁹

295. As punishment for its wrongdoing, McKesson agreed to pay a \$150 million fine and suspend the sale of controlled substances from distribution centers in several states.⁹⁰

⁸⁶ Department of Justice, Administrative Memorandum of Agreement, January 17, 2017, <https://www.justice.gov/opa/press-release/file/928476/download>, (accessed October 27, 2017).

⁸⁷ Department of Justice, *Administrative Memorandum of Agreement* at 4, *Supra*.

⁸⁸ *Id.*

⁸⁹ *Id.* at 6.

⁹⁰ *Id.* at 8.

296. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.⁹¹ In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed in its obligations.⁹² The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”⁹³

297. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

298. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.⁹⁴ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.⁹⁵ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate*

⁹¹ *Id.* at 4.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ U.S. Dep’t of Justice, Evaluation and Inspections Div., Office of the Inspector Gen., *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>, (accessed October 27, 2017).

⁹⁵ *Id.*

Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate*

Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;

- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

299. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.⁹⁶

300. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying

⁹⁶ Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.61697ec67e05; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.014176059151; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, <http://www.100daysinappalachia.com/2017/02/22/dea-agent-no-leadership-west-virginia-amid-flood-pain-pills/>, Charleston Gazette-Mail, Feb. 18, 2017, (all accessed October 27, 2017).

with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

301. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁹⁷ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results in favor of profits.

302. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”⁹⁸ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

303. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

304. Meanwhile, the opioid epidemic rages, causing injury to Plaintiff.

⁹⁷ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6d9936e87c93, (accessed October 27, 2017).

⁹⁸ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.0b845f727e2c, (accessed October 27, 2017).

305. The epidemic still rages because the fines and suspensions imposed by the DEA did not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, harming Plaintiff.

306. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers, causing diversion of opioid pain killers.

307. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

CAUSES OF ACTION

COUNT I

VIOLATION OF 18 U.S.C. § 1962(c), OPIOID DRUGS PROMOTION ENTERPRISE, PURSUANT TO THE RACKETEER INFLUENCED AND CORRUPT PRACTICES ACT (AGAINST ALL DEFENDANTS)

308. Plaintiff incorporates the allegations in all prior paragraphs in this Complaint as if they were fully set forth herein.

309. Defendants are “persons” within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Opioid Drugs Promotion Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

310. The Opioid Drugs Promotion Enterprise is an association-in-fact within the

meaning of 18 U.S.C. § 1961(4), consisting of Defendants (the Manufacturer Defendants and Distributor Defendants), including their employees and agents; Front Groups, including their employees and agents; and KOL's; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Drugs Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Defendants to fraudulently market Opioid drugs as scientifically proven as safe and effective. The Opioid Drugs Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioid Drugs Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the continuous sale of prescription opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioid Drugs Promotion Enterprise.

311. Each of the Defendants, in concert with the Front Groups, KOL's, as well as external and other as yet unknown marketing firms and distribution agents employed by, or associated with, Defendants in furtherance of the Opioid Drugs Promotion Enterprise, created and maintained systematic links for a common purpose-to aid in marketing Opioid drugs as safe for treatment of chronic pain, while suppressing evidence to the contrary and improperly inducing physicians to prescribe Opioid drugs for chronic pain. Each of the participants in the Opioid Drugs Promotion Enterprise received substantial revenue from the scheme to promote Opioid drugs as safe for its intended uses. Such revenue was exponentially greater than it would have been if Opioid drugs was marketed appropriately and the true safety risks of Opioid drugs disclosed. All participants of the Opioid Drugs Promotion Enterprise were aware of Defendants' control over the activities of the Opioid Drugs Promotion Enterprise in promoting Opioid drugs. Furthermore, each

portion of the enterprise benefited from the existence of the other parts.

312. The Opioid Drugs Promotion Enterprise engaged in and affected interstate commerce, because *inter alia*, it marketed, promoted, sold, or provided Opioid drugs to thousands of individuals and entities throughout the United States.

313. The named Defendants exerted control over the Opioid Drugs Promotion Enterprise and management of the affairs of the Opioid Drugs Promotion Enterprise.

314. Defendants conducted and participated in the affairs of the Opioid Drugs Promotion Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1512 (tampering with witnesses), and § 1952 (use of interstate facilities to conduct unlawful activity).

315. Defendants' fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting the safety of Opioid drugs so that Plaintiff paid for this drug for pain treatment and actively concealing and causing others to conceal, information about the true safety of Opioid drugs for such pain treatment. The Opioid Drugs Promotion Enterprise concealed from the public, consumers, prescribers, and TPPs the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioid Drugs Promotion Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

316. The persons engaged in the Opioid Drugs Promotion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues

to occur, through the use of interstate commerce by wires and mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioid Drugs Promotion Enterprise scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue the existence of the Opioid Drugs Promotion Enterprise.

317. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers and TPPs including Plaintiff. But for the Opioid Drugs Promotion Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

318. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and TPPs including Plaintiff. But for Opioid Drugs Promotion Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other

physicians. By failing to disclose this information, KOLs perpetuated the Opioid Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

319. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, terminate their role in the Opioid Drugs Promotion Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

320. The Front Groups and KOLs participated in the conduct of the Opioid Drugs Promotion Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions as set forth herein above to physicians, consumers, TPPs, and the general public in furtherance of the fraudulent scheme.

321. Defendants' use of interstate mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

- a. Communications with and among the enterprise participants that misrepresented the safety and risks of opioid drugs amongst themselves and others;
- b. communications with patients, Plaintiff's members, Plaintiff, and Plaintiff's affiliated healthcare providers, inducing payments for opioid drugs by misrepresenting the safety and risks of opioid drugs;
- c. receiving the proceeds in the course of and resulting from Defendants' improper scheme;
- d. transmittal and receipt of monies from TPPs, including without limitation Plaintiff,

as well as governmental health organizations and programs; and

- e. transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Opioid Drugs Promotion Enterprise.

322. At all times during the fraudulent scheme, Defendants and including without limitation the KOL's and the Front Groups had a legal and ethical obligation of candor to and honest dealing with public and TPPs, physicians and the medical community.

323. The conduct of the Opioid Drugs Promotion Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the Opioid Drugs Promotion Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

324. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiff. Each such racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiff. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiff.

325. Plaintiff has been injured in its property by reason of these violations in that Plaintiff paid hundreds of millions of dollars for Opioid drugs and for treatment related to opioid addiction and abuse that it would not have paid had Defendants not engaged in this pattern of racketeering activity.

326. The injuries to Plaintiff were directly and proximately caused by Defendants' racketeering activity.

327. Patients, physicians, pharmacy and therapeutic committee members, and TPPs, including Plaintiff, directly relied on the racketeering activities of the Defendants and the Opioid Drugs Promotion Enterprise. Plaintiff, both directly and indirectly, relied on the representations as to the efficacy and safety of Opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of Opioid drugs' efficacy and safety were based, other members of the medical community and consuming public were obligated to rely on Defendants' and the Opioid Drugs Promotion Enterprise's representations about Opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of Opioid drugs for chronic pain.

328. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiff for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

329. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff has suffered damages. Plaintiff is entitled to compensatory damages, costs and reasonable attorneys' fees, and any other appropriate relief available under 18 U.S.C. § 1962(c).

330. By reason of the foregoing, Plaintiff has been damaged by the Defendants in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH

SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for statutory damages, for attorneys' fees and costs expended herein, for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

COUNT II
VIOLATION OF 18 U.S.C. § 1962(d) - RICO CONSPIRACY PURSUANT
TO THE RACKETEER INFLUENCED AND CORRUPT PRACTICES ACT
(AGAINST ALL DEFENDANTS)

331. Plaintiff incorporates the allegations in all prior paragraphs in this Complaint as if they were fully set forth herein.

332. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

333. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Opioid Drugs Promotion Enterprise described previously through a pattern of racketeering activity. The Defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, the KOL's, the Front Groups, academics and other intermediaries to promote Opioid drugs for chronic pain, and suppress information about the harms known to result from opioid drugs use.

334. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff of money.

335. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962 (c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

336. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff has been and continues to be injured in its business or property as set forth more fully above.

337. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and
- d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

338. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and, upon information and belief, will continue into the future unless enjoined by this Court.

339. Plaintiff has been injured in its property by reason of these violations in that Plaintiff has paid hundreds of millions of dollars for Opioid drugs and the treatment related to the misuse, addiction and/or overdose of Opioid drugs that it would not have made had Defendants

not conspired to violate 18 U.S.C. § 1962(c).

340. Injuries suffered by Plaintiff were directly and proximately caused by Defendants' racketeering activity as described above.

341. Patients, physicians, pharmacy and therapeutic committee members, and TPPs, including Plaintiff, directly relied on the racketeering activities of the Defendants and the Opioid Drugs Promotion Enterprise. Plaintiff, both directly and indirectly, relied on the representations as to the efficacy and safety of Opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of Opioid drug's efficacy and safety were based, Plaintiff, as well as other members of the medical and consuming public were obligated to rely on Defendants' representations about Opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Opioid drugs.

342. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiff for three times the damages Plaintiff has sustained, plus the cost of this suit, including reasonable attorneys' fees.

343. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff has suffered damages. Plaintiff is entitled to compensatory damages, costs and reasonable attorneys' fees, and any other appropriate relief available under 18 U.S.C. § 1962(d).

344. By reason of the foregoing, Plaintiff has been damaged by the Defendants in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for statutory damages, for attorneys' fees and costs expended herein, for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

COUNT III
FRAUD
(AGAINST ALL DEFENDANTS)

345. Plaintiff incorporates the allegations Paragraphs 1 through 307 in this Complaint as if they were fully set forth herein.

346. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff upon which Plaintiff did rely, in order to induce the Plaintiff to pay to cover the purchase and consumption of opioids to treat the chronic pain of Plaintiff's members. Defendants'

misrepresentations and omissions of facts include, *inter alia*:

- Marketing dangerous and ineffective opioid drugs as safe and effective for the long-term treatment of chronic pain conditions in order to deceive physicians into prescribing addictive opioids to Plaintiff's members;
- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of federal law;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

347. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

348. Defendants intended that Plaintiff and Plaintiff's members would rely on their misrepresentations and omissions and Plaintiff and Plaintiff's members did, in fact, rely upon those material misrepresentations and omissions to their detriment.

349. Given the incredible resources Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and Plaintiff's members reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

350. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and Plaintiff's members reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

351. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

352. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those it would have otherwise incurred, payments for its members' treatment for opioid addiction, and payments for emergency hospital visits for its members, including payments for Naloxone Hydrochloride

(Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

COUNT IV
CONSPIRACY TO COMMIT FRAUD
(AGAINST ALL DEFENDANTS)

353. Plaintiff incorporates the allegations within Paragraphs 1 through 307 and Paragraphs 345 through 352 in this Complaint as if they were fully set forth herein.

354. At all relevant times, the Manufacturer and Distributor Defendants, along with the KOLs they assisted and controlled, agreed to conceal or omit and misrepresent information regarding the health effects or addictive nature of their respective prescription opioid drugs or both,

with the intention that the Plaintiff and the public would rely on the information to their detriment.

355. The Defendants' actions, and those of the KOLs, constitute a successful conspiracy to commit fraud by concealment.

356. Specifically, Defendants agreed and conspired to misrepresent and/or conceal material facts concerning the addictive and dangerous nature of their prescription opioid drugs, to consumers, including Plaintiff and its members, with the knowledge of the falsity of their misrepresentations.

357. At all relevant times, upon information and belief, the misrepresentations and concealments concerning their prescription opioid drugs that were manufactured, distributed, promoted and/or sold by the Defendants include, *inter alia*:

- a. The Defendants intentionally misrepresented to Plaintiff and the public the truth about how opioids lead to addiction;
- b. The Defendants knowingly misrepresented that opioids improve function;
- c. The Defendants misrepresented that addiction risk can be managed;
- d. The Defendants misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. The Defendants falsely claimed that withdrawal is simply managed;
- f. The Defendants misrepresented that increased doses pose no significant additional risks; and
- g. The Defendants falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

358. At all relevant times, the Defendants actively, knowingly, and intentionally agreed and conspired to conceal and misrepresent these material facts to the Plaintiff and the consuming

public with the intent to deceive the Plaintiff and public, and with the intent that consumers would purchase and use their prescription opioid drugs.

359. At all relevant times, the consuming public, including Plaintiff, would not otherwise have purchased or used these addictive and dangerous opioid drugs for long-term chronic pain management had they been informed of the risks associated with the use of these drugs.

360. At all relevant times, Plaintiff relied on the Defendants' misrepresentations concerning the safety and efficacy of these prescription opioid drugs, and its reliance was reasonably justified.

361. As a direct and foreseeable consequence of Defendants' conspiracy to commit fraud, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those it would have otherwise incurred, payments for its members' treatment for opioid addiction, and payments for emergency hospital visits for its members, including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC.,

ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for interest, and for such other and further relief which Plaintiff may show to be justly entitled.

COUNT V
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

362. Plaintiff incorporates the allegations within Paragraphs 1 through 307 in this Complaint as if they were fully set forth herein.

363. Plaintiff conferred a benefit on Defendants by paying for opioids manufactured by the Manufacturer Defendants and distributed by the Distributor Defendants.

364. In exchange for the inclusion of opioid prescriptions as a covered health insurance benefit and the payments made by Plaintiff, Plaintiff expected that Defendants had provided all of the necessary and accurate information regarding the risks of opioids and had not misrepresented any material facts regarding those risks.

365. Defendants' intentional conduct directly caused Plaintiff to suffer increased expenditures to cover the costs of opioid related healthcare, including addiction treatment.

366. It would be inequitable under these circumstances for the Defendants to retain these benefits without paying Plaintiff for its value.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON &

JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

COUNT VI
NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

367. Plaintiff incorporates the allegations within Paragraphs 1 through 307 of this Complaint as if they were fully set forth herein.

368. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids, as provided by state and federal law, to avoid, prevent, or attenuate third-party misconduct.

369. Distributor Defendants breached this duty by failing to take any action to prevent or reduce the distribution of opioids, as required by state and federal law, and instead participated in and enabled Defendants' misconduct.

370. The Distributor Defendants placed their profit motives above their legal duty and

enabled, encouraged and caused the over-prescribing and distribution of opioids.

371. The Distributor Defendants negligently failed to perform their duty to help to prevent the over-prescribing of opioids and/or acted with gross negligence.

372. As a proximate result, Distributor Defendants and its agents have caused Plaintiff to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. Plaintiff has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and prescriptions.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, and WALGREENS BOOTS ALLIANCE, INC. A/K/A WALGREEN CO., for damages in excess of seventy-five thousand dollars (\$75,000), for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

COUNT VII
NEGLIGENCE
(AGAINST MANUFACTURER DEFENDANTS)

373. Plaintiff incorporates the allegations in Paragraphs 1 through 307 in this Complaint as if they were fully set forth herein.

374. The Manufacturer Defendants, at all times material, manufactured, designed, formulated, marketed, tested, promoted, supplied, sold, and/or distributed their respective prescription opioid drugs in the regular course of business.

375. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and sale of their respective prescription opioid drugs.

376. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable

care and to warn the Plaintiff and the consuming public of the risk, dangers and addictive nature of their respective prescription opioid drugs.

377. At all relevant times, the Manufacturer Defendants knew or should have known that their respective prescription opioid drugs were unreasonably dangerous and defective for long-term chronic pain treatment and when used in a reasonably foreseeable manner.

378. The Manufacturer Defendants breached their duty to Plaintiff and were otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and/or sale of their respective prescription opioid drugs, which were inherently dangerous and defective, and unfit and unsafe for their intended and reasonably foreseeable uses.

379. The Manufacturer Defendants were further negligent in failing to accompany their respective prescription opioid drugs with proper warnings or adequate labeling regarding the dangerous and potentially fatal health risks associated with the use of their respective prescription opioid drugs, particularly when used for long-term chronic pain treatment, which was their intended or reasonably foreseeable use.

380. The Manufacturer Defendants were a proximate cause of the over-prescribing of the opioids and, hence, the millions of dollars in inappropriate prescriptions and other related health care costs paid for by Plaintiff.

WHEREFORE, Plaintiff, SAN FRANCISCO HEALTH PLAN, prays for judgment against Defendants, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., ENDO HEALTH

SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, and SPECGX LLC, for damages in excess of seventy-five thousand dollars (\$75,000), for interest, and for such other and further relief to which Plaintiff may show to be justly entitled.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable by right.

Dated: October 18, 2019

Respectfully submitted,

Solowsky & Allen, P.L. <i>Counsel for Plaintiff</i> RICHARD L. ALLEN, ESQ. Florida Bar Number: 295485 LAUREN KAIN WHALEY, ESQ. Florida Bar Number: 88670 201 S. Biscayne Boulevard Suite 915 – Citigroup Center Miami, Florida 33131 Telephone No.: (305) 371-2223 Facsimile No.: (305) 373-2073 Email: rallen@salawmiami.com Email: mlopez@salawmiami.com Email: lkain@salawmiami.com By: <u>/s/ Richard L. Allen</u> RICHARD L. ALLEN	Mansfield Bronstein & Stone, LLP <i>Counsel for Plaintiff</i> GARY N. MANSFIELD, ESQ. Florida Bar Number: 61913 500 East Broward Boulevard, Suite 1450 Fort Lauderdale, Florida 33394 Telephone No.: (954) 601-5600 Facsimile No.: (954) 961-4756 Email: gary@mblawpa.com Service Email Designation: litigation@mblawpa.com By: <u>/s/ Gary N. Mansfield</u> GARY N. MANSFIELD
---	--